

**1638. Misbranding of Vivogen. U. S. v. 173 Cases of Vivogen, and a number of booklets. Consent decree of condemnation. Product ordered released under bond.** (F. D. C. No. 15358. Sample Nos. 28319-H, 28324-H.)

**LABEL FILED:** March 19, 1945, Western District of Washington.

**ALLEGED SHIPMENT:** On or about January 26 and February 2, 1945, by the Vivogen Co., from Los Angeles, Calif.

**PRODUCT:** 173 cases, each containing 4 1-gallon bottles, of *Vivogen*, together with accompanying booklets entitled, "Astonishing New Discoveries about Sickness which are Beneficial to Good Health \* \* \* *Vivogen*," at Seattle, Wash. Analysis showed that the product consisted of diluted lime water and contained 0.07 gram of calcium hydroxide in each 100 cc.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), because of false and misleading statements in the accompanying booklets which represented, suggested, and implied that the article would be efficacious in removing the causes and in the treatment of throbbing headaches, colds, catarrh, sinus troubles, ringing in the ears, impaired sight, vertigo, gall bladder pains, varicose veins, itching skin, aching bones, numb scalp, chapped hands, rash, eczema, sunburn, burns, cuts or scratches, abrasions, sprains, swellings, colds in the chest or head, chronic sores, acute abdominal pains, common fevers, influenza, pneumonia, ptomaine poisoning, constipation, high blood pressure, kidney and bladder troubles, Bright's disease, diabetes mellitus, asthma, cancer, arthritis, severe stomach trouble, gallstones, liver trouble, kidney trouble, stomach ulcers, mastoids, sore throat, blood poisoning, la grippe, neuritis, catarrh, rheumatism, and tumors. The article would not be efficacious for the purposes represented, suggested, and implied.

Further misbranding, Section 502 (e) (2), the product was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

**DISPOSITION:** April 11, 1945. The Vivogen Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered relabeled under the supervision of the Food and Drug Administration.

**1639. Misbranding of Glanzyme. U. S. v. 26 Bottles of Glanzyme. Decree of condemnation and destruction.** (F. D. C. No. 15141. Sample Nos. 80955-F to 80958-F, incl.)

**LABEL FILED:** February 7, 1945, Western District of Oklahoma.

**ALLEGED SHIPMENT:** Between the approximate dates of October 1 and December 21, 1944, from Lynwood, Calif., by the Ryer Dietary Supplements Co.

**PRODUCT:** 9 bottles of *Glanzyme No. 1*, 6 bottles of *Glanzyme No. 2*, 9 bottles of *Glanzyme No. 3*, and 2 bottles of *Glanzyme No. 6* at Oklahoma City, Okla. The products were accompanied, when introduced into and while in interstate commerce, by a booklet entitled "Vitamin, Mineral and Glandular Therapy."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements in the booklet were false and misleading since they represented and suggested (1) that the *Glanzyme No. 1* would serve as a female sex hormone supplement; that it would remedy subnormal sexual growth or development, or menstrual disturbances characterized by the absence of menstrual flow, or painful menstruation; that it would supplant the falling off of hormone flow throughout the pituitary-suprarenal-ovarian cycle in menopause; and that it would relieve the tension and discomfort caused by the upset condition attendant upon the change of life; (2) that the *Glanzyme No. 2* would be effective in the treatment of abnormal conditions attendant upon pregnancy and in the treatment of threatened abortion, or excessive menstruation (menorrhagia); (3) that the *Glanzyme No. 3* would be effective in the treatment of neurasthenia, mental apathy, and impotence; and (4) that the *Glanzyme No. 6* would be effective to supplement the adrenal glands and their functions; and that it would be effective as an aid in suprarenal deficiencies. The articles would not be efficacious for the purposes claimed.

Further misbranding, Section 502 (a), the subdesignation "Asthmazyme," appearing on the bottle label of the *Glanzyme No. 6* and in the booklet, was misleading since it represented and suggested that the *Glanzyme No. 6* would be an adequate treatment for asthma, whereas it would not be an adequate treatment for asthma.

Further misbranding, Section 502 (a), the designation "Glanzyme," appearing on the bottle labels of all the articles and in the booklet, was misleading

since the articles would not supply any glandular or enzymic activity and would have no therapeutic significance when consumed as directed in the labeling, "3 to 5 tablets daily or as directed by a Specialist," except for the content of iron in the *Glanzyme No. 2*; and the following statements on the bottle labels of the articles and in the booklet were misleading since the articles, when consumed as directed, would produce no therapeutic effect, and the listed ingredients were therefore not active except as to the ingredient, reduced iron, in the *Glanzyme No. 2*: (*Glanzyme No. 1*) "Active Ingredients Ovarian Residue . . . . 3 Gr. Whole Suprarenal . . . . 1 Gr. Anterior Pituitary . . . . ½ Gr. Kelp . . . . 1 Gr. Alfalfa . . . . 2 Gr. Papain (Papaya-Enzyme) . . . . 1 Gr."; (*Glanzyme No. 2*) "Active Ingredients Mammary . . . . 3 Gr. Placenta . . . . 2 Gr. Whole Pituitary . . . . ½ Gr. Kelp . . . . 1 Gr. Papain (Papaya-Enzyme) . . . . 1 Gr. Alfalfa . . . . 2 Gr. Reduced Iron . . . . ½ Gr. (22 Mg.)"; (*Glanzyme No. 3*) "Active Ingredients Orchic . . . . 4 Gr. Prostate . . . . 2 Gr. Whole Suprarenal . . . . 1 Gr. Anterior Pituitary . . . . ½ Gr. Kelp . . . . 1 Gr. Papain (Papaya-Enzyme) . . . . 1 Gr. Alfalfa . . . . 1 Gr."; (*Glanzyme No. 6*) "Active Ingredients Whole suprarenal . . . . 2 Gr. Papain (Papaya-Enzyme) . . . . ½ Gr. Kelp . . . . 1½ Gr. Alfalfa . . . . 4 Gr."

DISPOSITION: May 8, 1945. The sole intervener having consented to the entry of a decree, judgment of condemnation was entered and the products, together with the booklet, were ordered destroyed.

**1640. Misbranding of SNJ Sulfathiazole Nasal Jelly. U. S. v. 11½ Dozen, 11¼ Dozen, and 11½ Dozen Packages of SNJ Sulfathiazole Nasal Jelly. Default decrees of condemnation and destruction.** (F. D. C. Nos. 15799, 15800, 16063. Sample Nos. 6329-H, 27351-H, 27352-H.)

**LIBELS FILED:** April 16 and 26, 1945, District of Oregon and Eastern District of New York.

**ALLEGED SHIPMENT:** Between the approximate dates of July 21, 1944, and February 12, 1945, by the S. N. J. Products Co., from Los Angeles, Calif.

**PRODUCT:** 23 dozen packages of *SNJ Sulfathiazole Nasal Jelly* at Portland, Oreg., and 11¼ dozen packages of the same product at Brooklyn, N. Y. Examination disclosed that the product possessed the composition stated upon its label.

**LABEL, IN PART:** "SNJ Sulfathiazole Nasal Jelly \* \* \* Contains 3% Sodium Sulfathiazole and ¼<sub>10</sub>% Benzoate of Soda in a water soluble base."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements on the label and in the circular entitled, "Directions For Use," enclosed in the package, were false and misleading since they represented and suggested that the article would be an adequate treatment for the various disease conditions affecting the nose and throat; and that it would be effective in the relief and prevention of colds and sinus trouble. The article would not be an adequate treatment, and it would not be effective for the conditions represented. The name of the article was misleading since its labeling failed to reveal the fact, material in the light of such name, that the article was not, because of its sulfathiazole content, of value for disease conditions affecting the nose.

DISPOSITION: May 24 and June 23, 1945. No claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

**1641. Misbranding of Sinudrene. U. S. v. 5 Dozen Bottles and 3¾ Dozen Bottles of Sinudrene. Default decree of condemnation and destruction.** (F. D. C. No. 15085. Sample Nos. 93228-F, 93229-F.)

**LIBEL FILED:** January 25, 1945, Southern District of West Virginia.

**ALLEGED SHIPMENT:** On or about April 17 and November 28, 1944, by Davart Products, from Ashland, Ky.

**PRODUCT:** 5 dozen 1-ounce bottles and 3¾ dozen 2-ounce bottles of *Sinudrene* at Charleston, W. Va. Examination of samples disclosed that the product consisted essentially of ephedrine, water, glycerin, small amounts of phenol and iodides, and trace of malachite green.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the label statements, "Sinudrene \* \* \* for the relief of painful and congested sinus conditions. Promotes Drainage \* \* \* In severe cases \* \* \* allow Sinudrene to penetrate the sinuses more quickly. \* \* \* Simple Hay Fever and Catarrh," were false and misleading since the product would not be effective in the treatment of painful and congested sinus conditions, hay fever, and catarrh, and would not be effective to promote drainage.